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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/369,410	08/05/1999	RODNEY K. HEHENBERGER	54982US1A002	6752

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EXAMINER	
HANDY, DWAYNE K	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/369,410	HEHENBERGER ET AL.	
	Examiner	Art Unit	
	Dwayne K Handy	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Inventorship

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 21-34 and 36-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Augurt (5,200,147) in view of Sandstrom et al. (5,631,171). Augurt teaches a chemical indicator test sheet (30) comprised of a flat surface capable of reflecting energy and having a sterilizing agent sensitive ink. For the purpose of quantifying color changes in the indicator test sheet, it is suggested that the sheet be analyzed with a reflectometer. Augurt does not teach any specific elements of the reflectometer however.

Sandstrom teaches an instrument configured and arranged to detect a change in the thickness or refractive index of a substrate. The device is best shown in Figures 13-15 and described in column 39-42. From columns 39-40:

Referring to FIG. 13, there is shown a prior art method for detecting interaction of a light with a test surface. In the prior art, two polarizer were provided to allow such detection. Specifically, #1 corresponds to the white light source used in this prior art instrument. A standard halogen lamp is used to generate the polychromatic light. The light is incident on the polarizer at position #2, and is then linearly polarized. The linearly polarized light then impinges on the reference surface #3 which is at 70.degree. with respect to the test surface #4. The linearly polarized light is reflected from the reference surface (#3) as elliptically polarized light. The light then impinges the test surface (#4) and is reflected to the second polarizer at position #5. The interaction of the light with test surface (#4) inverts the s- and p- components of the elliptically polarized light. The polarizer at position #2 and #5 are matched and #5 is rotated 90.degree. relative to #2. Light which is reflected from the test surface #4 which matches that reflected from the reference surface #3, will pass through polarizer #5 and be completely extinguished at the detector (#6). If there are any differences in the surface properties of surfaces #4 and #3, then some residual ellipticity will cause an increase in intensity to be measured at the detector #6.

Such an instrument which is useful for analysis of thin films and changes in film characteristics is the Comparison Ellipsometer described in U.S. Pat. Nos. 4,332,476, 4,655,595 and 4,647,207. The optical pathway of such instruments is shown in FIG. 13, as discussed above. This instrument can use a reference surface with a wedge of thicknesses across the surface. If thickness values are scribed onto the wedge, the thickness of a test surface may be determined relative to the wedge. The test surface thickness equals the wedge thickness at the point where light is extinguished at the detector.

The instrument operates on the basis of comparing the degree of elliptical polarization, caused by the reflection of plane polarized polychromatic light, between two surfaces. Incident

polychromatic light is collimated and plane polarized. The polarized light is reflected at an oblique angle from the reference surface, which is a reflective substrate with similar or identical optical characteristics to that of the test piece. The reflected light is then elliptically polarized as a result of reflection. The elliptically polarized light then reflects from the test surface. The test surface and reference surface are arranged perpendicular to one another such that after reflection from the test surface, the light is once again plane polarized where the test and reference surfaces are optically identical. If their thickness and/or refractive indices are not identical, the light retains some elliptical character. The ellipticity is a function of the refractive index and the thickness differences. A second polarizer is then used to filter the light, and removes the plane polarized light corresponding to identical films. An increase in ellipticity will result in greater light transmission through the second polarizer. Thus, a change in thickness or refractive index is transformed into a change in light intensity which may then be measured using conventional techniques. By employing the Comparison Ellipsometer in this fashion, resolution to .+-.5.ANG. may be achieved. Unlike conventional ellipsometry, the Comparison Ellipsometer is designed to allow broad field measurements. This feature allows simultaneous measurement of the entire reaction zone. Therefore, measurement errors do not arise because of non-homogeneous binding or reaction patterns.

For the applications of this invention, a more useful reference surface is one which is uniform. When a test surface to be analyzed has all the components for colored signal generation for visual interpretation, the reference surface must also contain the optical thin film coating. This additional coating is not required for the instrumented analysis. To maximize the signal produced by a change in thickness or mass on the test surface, the reference standard should be approximately 50 to 100.ANG. thinner than the test surface, substrate, attachment layer, and receptive material. If these two surfaces are too closely matched, then a small change in thickness or mass will result in only a small increase in intensity relative to the original background intensity. The change in intensity for small thickness changes is dramatically increased when the background intensity is above a certain minimum or is sufficiently bright. With this reference surface all changes in thickness or mass cause a dramatic change in intensity of light measured by the detector relative to the test surface's initial reading. The change in intensity may reflect an increase in thickness or a decrease depending on the application, see Examples 8, 12, 13, 16, and 17. The instrumented reading protocols are given in Example 21.

For the analysis of specific binding reactions on a test surface, a number of modifications greatly improve the performance of the comparison Ellipsometer. The original design relied on the observer's eye for inspection of the surface.

Referring to FIGS. 14A and 14B, there are shown two devices in which no polarizer are provided, and in which a thin film can be analyzed either with a single photodiode, an array, or a CCD detector array, or with a reflectometer a photomultiplier detector.

The detector may be mounted where the eyepiece is located in the original instrument. It may also be mounted at 90.degree. to the side of the light path by incorporation of a partially silvered mirror or beamsplitter set at 45.degree. to reflect a portion of light to a detector, and the rest to the eyepiece for visual alignment of samples. If the mirror is inserted into the optical path, the spot intensity reaching the detector will be only a fraction of the light available. If the detector is directly in the optical pathway without a mirror, 100% of the sample intensity reaches the

detector. When a beamsplitter and eyepiece are included in the apparatus, if care is not taken, stray light can be introduced which degrades the optical signal incident on the detector.

A photodiode array may be programmed to dedicate individual photodiodes to measure the intensity of reaction zones or spots, while other photodiode arrays measure the background, or control zones. Simultaneous measurement of the spot intensity and the background intensity allows each reading to be accurately corrected for test surface background.

Sandstrom, then, teaches an instrument which contains an illumination source, a detector, a positioning means, a controller, and a processing means. The Ellipsometer referred to by applicant and incorporated into the reference contains the control and processing means - a computer. The computer would also include memory means and microprocessing capabilities. The illumination source is capable of providing multiple wavelengths of light (col. 39, line 45) and capable of providing light at the angles required by applicant. It would have been obvious to one of ordinary skill in the art to combine the apparatus of Sandstrom with the indicator of Augurt. One would add the apparatus of Sandstrom to automate the reading of the Augurt indicator as suggested by Augurt. As to the computer containing sterilization data, it would have been obvious to one of ordinary skill in the art to provide calibration data given that Augurt teaches the reading of a sterilization indicator that changes color in response to being sterilized.

4. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Augurt (5,200,147) and Sandstrom et al. (5,631,171) and further in view of Ozawa et al. (5,690.893). Augurt and Sandstrom as combined above teach every element of claim 35 except for a complementary CMOS circuit for use with the processing means. Ozawa et al. teach an analyzer for examining a sensor, column or **reagent** which

specifies and analyzing condition. The result of the analysis may be written into an element which is provided with the analyzed member. In column 6, Ozawa teaches that the data may be stored in a non-volatile memory source such as CMOS memory. It would have been obvious to one of ordinary skill in the art to provide a CMOS memory with the combined teachings of Augurt and Sandstrom. The addition of the CMOS memory would provide a non-volatile form of storing the data from analyzing the sterilization indicator.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
June 28, 2004

Jill Warden
Supervisory Patent Examiner
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